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Peter Andrew Priest

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CHICAGO, IL 60606

EXAMINER

CHAPMAN, GINGER T

ART UNIT

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3761

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,839	Applicant(s) PRIEST ET AL.	
	Examiner Ginger T. Chapman	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-39 is/are pending in the application.
- 4a) Of the above claim(s) 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 July 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3761

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Group I, claims 20-38 in the reply filed on 13 September 2010 is acknowledged. The traversal is on the ground(s) that the fields of search should overlap. This is not found persuasive because the invention of Group I, claims 20-38 are drawn to an apparatus classified in class 604, subclass 342; the invention of Group II, claim 39, is drawn to methods of connecting a drain bag to a subject, classified in class 604, subclasses 174, additionally, the invention of Group I is drawn to a different statutory class than the invention of Group II. Because more than one invention is claimed in one and the same national application, the inventions identified as Group I and Group II are in different statutory classes and the searches for each group are not coextensive, there will be a burden on the examiner due to searching multiple inventions for one and the same national application.

The requirement is still deemed proper and is therefore made FINAL.

Claim 39 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 13 September 2010.

Status of the Claims

Claims 20-39 are pending in the application, claim 39 is withdrawn from consideration as being drawn to a nonelected invention, claims 20-38 are examined on the merits.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims.

Art Unit: 3761

Therefore, the “means for applying force” see **claim 1**; “the means for applying force is a belt or abdominal strap” see claim 2 and PG-Publication paragraph [0018] must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Therefore, the “formations for complementary inter-engagement with corresponding formations” see **claim 28**; and PG-Publication paragraph [0042] must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Therefore, the “outlet flange adapted for snap-fit engagement” see **claim 29**; and PG-Publication paragraph [0042] must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Therefore, the “screw-fit engagement” see **claim 30**; and PG-Publication paragraph [0042] must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Therefore, the “connector formed or provided with an element or member of porous material adapted to allow passage of gases” see **claim 35**; and PG-Publication paragraph [0041] discussing a filter 21 on drainage bag 19; however the instant Specification contains no disclosure of the connector formed or provided with an element or member of porous material, therefore the connector formed with a porous element or member must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing

Art Unit: 3761

should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-26, 28-29, 31, 34, 36 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Jensen (EP 0 098 718 A1).

With respect to claim 20, as best depicted in Figures 1 and 4-6, Jensen discloses an apparatus for connecting a drainage bag 10 to a fistula of a subject (page 16, lines 3-11), including a connector (Figures 3-6) in the form of an elongate flexible tubular member 36 (page 20, lines 15-20; Figures 1, 3 and 6) having an inlet aperture 34 (page 17, lines 22-24; Figures 1 and 3) at a proximal end 29 (page 17, lines 14-15) for receiving waste material from the fistula and an outlet aperture 38 (page 18, lines 7-9) at a distal end 32 for engagement 18 with the

Art Unit: 3761

drainage bag 10 through which waste material travels before entering the drainage bag (page 17, lines 22-24; Figure 3-6), and means 22 for applying a force to the connector for pressing the proximal end of the connector into contact with the exterior surface of the subject whereby to connect it to the fistula (page 16, lines 20-23).

With respect to claim 21, Jensen discloses wherein the means 22 for applying a force to the distal end of the connector is a belt or abdominal strap (page 16, lines 20-23).

With respect to claim 22, as best depicted in Figure 6, Jensen discloses wherein the flexible tubular member 36 is resiliently deformable in a longitudinal direction (page 20, lines 14-25).

With respect to claim 23, as best depicted in Figures 3-6, Jensen discloses wherein at least a portion 46 of the flexible tubular member 36 is ribbed (page 21, lines 16-23).

With respect to claim 24, Jensen discloses wherein the apparatus further includes an inlet flange 26 (Figures 1 and 2); 86 (Figure 6) around the inlet aperture 34 (page 17, lines 10-24).

With respect to claim 25, Jensen discloses wherein the inlet flange 26, 86 (Figures 1, 2 and 6) is resiliently deformable 28, 88 (page 17, lines 10-11; page 18, lines 16-17; page 20, lines 1-4).

With respect to claim 26, as best depicted in Figures 2 and 6, Jensen discloses wherein the apparatus further includes an outlet flange 33 around the outlet aperture 38 (page 18, lines 7-15).

Art Unit: 3761

With respect to claim 28, as best depicted in Figure 2, Jensen discloses wherein the outlet flange 33 is provided with formations 31, 32 for complementary inter-engagement with corresponding formations 20 on a drainage bag 10 (page 17, lines 14-24).

With respect to claim 29, as best depicted in Figure 2, Jensen discloses wherein the outlet flange 33 is adapted for snap-fit engagement with a drainage bag 10 (page 17, lines 18-24).

With respect to claim 31, Jensen discloses wherein the flexible tubular 36 member is variable in length (page 20, lines 15-19; page 21, lines 16-18; page 23, lines 16-20).

With respect to claim 34, Jensen discloses wherein the connector (Figures 1 and 3) is formed, at least in part, of a flexible plastics or rubber or foam material (page 18, lines 16-17; page 20, lines 1-4, lines 19-20 and lines 24-26).

With respect to claim 36, Jensen discloses wherein the connector is formed, at least in part, of a hypo-allergenic material (page 2, line 27 to page 3, line 1).

With respect to claim 38, as best depicted in Figure 1, Jensen discloses drainage appliance 33 comprising apparatus according to claim 20 interconnected with a drainage bag 10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 3761

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen (EP 0 098 718 A1).

With respect to claim 32, Jensen discloses the claimed invention except for expressly disclosing wherein the length of the flexible tubular member may be varied by up to 4 cm in length. Jensen discloses varying the length of the tubular member as the member extends, thus providing motivation for such (page 24, lines 13-20).

At page 4, lines 12-18 Jensen discloses the fistula area and skin surrounding a stoma/fistula is sensitive and painful; at page 7, line 26- page 8, line 5, that a disadvantage is when the pouch inner wall surface contacts the stoma and thus the pouch surface should be maintained at a position spaced from the stoma; at page 9, lines 20-30, the connector is of sufficient strength to maintain the pouch at a sufficient distance from the stoma and the connector extends such a distance; at page 12, lines 9-15, discloses that the connector, when extended, the flexible tubular member maintains the pouch at a location spaced from the fistula/stoma; At page 13, lines 16-21, the connector should have strength sufficient aid in supporting the pouch as the pouch becomes heavier due to accumulation of waste therein; at page 23, line 26 to page 24, line 9, discloses that the only limitation on the length of the connector is that it must have sufficient strength to withstand the weight of the pouch.

Thus Jensen provides motivation to vary the length of the flexible tubular member balanced between a length sufficient to keep the pouch away from the stoma and a length

Art Unit: 3761

whereby the weight of the filling pouch is supported by the member, thus disclosing the general conditions of the claim of varying the length of the flexible tubular member. Any particular length will also vary depending on the condition of a wearer's fistula and degree of sensitivity or pain. Therefore, in view of the teachings of Jensen, it would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the length of the flexible tubular member as taught by Jensen by up to 4 cm in length as claimed in order to provide a connector that protects the fistula while still supports the weight of the pouch, and since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen (EP 0 098 718 A1) in view of Olsen (US 5,501,678).

With respect to claim 27, Jensen discloses the claimed invention except for the outlet flange is provided with an adhesive layer on at least a portion thereof for adhesive engagement with a drainage bag. Jensen discloses the outlet flange 33 is provided with formations for complementary inter-engagement with corresponding formations on a drainage bag, thereby providing motivation to engage the outlet flange with the drainage bag. Olsen, at column 1, lines 5-10 and lines 37-40, teaches a connector that can be adhered to the skin of a user, a collection bag or a coupling part therefor being adhered to the appliance side of the connector and thus provides motivation for adhesive engagement with a flange and drainage bag. Olsen teaches, at column 4, lines 10-14, teaches the equivalency of using either adhesive or interengaging coupling parts to provide engagement between fistula / stoma connectors and drainage bags. As

Art Unit: 3761

best depicted in Figure 2, Olsen teaches an outlet flange 10 provided with an adhesive layer 21 on at least a portion thereof for adhesive engagement with a drainage bag (column 2, lines 42-47; column 4, lines 1-20). Therefore it would have been obvious to one having ordinary skill in the art to provide the engagement between the connector and drainage bag with adhesive of Olsen for the engagement of Jensen since Olsen teaches their equivalency and both methods perform the substantially identical function of providing engagement and it has been held that substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency. *In re Siebentritt*, 152 USPQ 618 (CCPA 1967).

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen in view of Brooks (US 5,312,381).

With respect to claim 30, Jensen discloses the claimed invention except for the outlet flange is adapted for screw-fit engagement with a drainage bag. Jensen discloses the outlet flange is adapted for snap fit, frictional fit between formations for complementary inter-engagement with the drainage bag, thus providing motivation for engagement. As best depicted in Figures 2 and 4-5, Brooks teaches a connector 10 having outlet flange adapted for screw-fit 21, 22 engagement 31, 40 with a drainage bag 41 (column 2, lines 3-8; column 3, lines 15-19 and lines 46-47 and lines 52-61). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the screw-fit engagement of Brooks for the engagement of Jensen since Brooks states, at column 1, lines 36-39, that the benefit of this type of engagement is that assembling the connector may be less painful to a stoma than the force required to snap fit prior art connectors.

Art Unit: 3761

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen in view of Kay (US 4,592,750).

With respect to claim 33, Jensen discloses the claimed invention except for a retention member to prevent movement of an intestine of the subject through the connector into the drainage bag. Jensen, at page 7, lines 26-28, provides motivation to prevent the stoma, i.e. fistula from unnecessary contact with the pouch of the apparatus. Kay, at column 3, lines 4-6, provides motivation to protect the stoma / fistula from pain and injury resulting from contact with surfaces during daily activity, thus providing motivation for such. As best depicted in Figures 1 and 5-10, Kay teaches a connector 22 comprising retention member 38 which prevents fistula/stoma contact and also would perform the function of preventing movement of an intestine of the subject through the connector while still permitting outflow of stomal waste through the connector (column 5, lines 14-30). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the retention member of Kay for the connector of Jensen since Kay states, at column 5, lines 24-29, that the benefit of providing such a member is that it prevents the stoma from contact, i.e. the stoma cannot protrude past the member, while still permitting stomal outflow, thereby providing a more sanitary and comfortable appliance.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen in view of Mulhauser et al (EP 1 346 711 A1).

With respect to claim 35, Jensen discloses the claimed invention except for wherein the connector is formed or provided with, at least in part, with an element or member of porous material adapted to allow passage of gases therethrough but prevent substantial egress of liquid.

Art Unit: 3761

As best depicted in Figure 3-5, Mulhauser teaches a connector 16 provided with an element or member 30 of porous material adapted to allow passage of gases therethrough but prevent substantial egress of liquid (column 8, paragraph [0058], teaching activated carbon filter, carbon is a porous material generally used for conventional ostomy filters). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the appliance of Jensen with a filter as taught by Mulhauser since Mulhauser states, at column 8, paragraph [0058], that the benefit of providing filters in ostomy appliances is that the flatus gas released by the wearer is filtered therethrough, thereby providing a more sanitary appliance.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen in view of von Dyck (US 6,033,390).

With respect to claim 37, Jensen discloses the claimed invention except for the connector is formed, at least in part, of foam. Jensen discloses, at page 17, lines 6-13, providing the connector with a porous material in contact with the wearer's skin around the stoma, thus providing motivation for a porous type of material which can be foam as foam is known to be porous material, but does not expressly disclose any particular foam. As best depicted in Figures 4 and 11, von Dyck teaches a connector (Figure 11) formed at least in part, of foam 58 (Figure 4; column 9, lines 1-15). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the connector of Jensen with a foam part as taught by von Dyck since von Dyck states, at column 9, lines 1-7, that the benefit of such is that the foam protects the sensitive skin of the stoma and additionally provides some cushioning between the skin and the appliance, thereby providing a more comfortable, less painful appliance.

Art Unit: 3761

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Smith et al (US 3,216,420) Figures 2, 6 and 9; Arnone et al (US 4,642,107) Figure 3; Steer (US 4,952,216) Figure 1; Steer et al (US 4,232,672) Figures 1 and 2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/
Examiner, Art Unit 3761
11/17/10

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3761

Application/Control Number: 10/585,839

Page 13

Art Unit: 3761